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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	19

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/441,966	HALL ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 15-18* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-11 and 15-18 are pending in the application.

[2] Applicants' amendment to the specification, cancellation of claims 12-14, and amendment to claims 1 and 15-18 in Paper No. 16, filed October 02, 2002, is acknowledged.

[3] Receipt of an amended paper copy of the sequence listing filed September 09, 2002, is acknowledged.

[4] Receipt of a petition under 37 CFR 1.144 filed as Paper No. 17 is acknowledged. The petition requests withdrawal of the restriction requirement as set forth in Paper No. 11. Applicants' petition was subsequently denied in an Office communication filed as Paper No. 18. Therefore, claims 1-10 and 15-18 are being examined to the extent the claims read on the elected subject matter (Group XVI of the restriction of Paper No. 11). Applicants' arguments at pages 4-5 of Paper No. 16 addressing the restriction requirement are acknowledged. In response to applicants' arguments the examiner refers applicants to the decision in the Office communication of Paper No. 18.

[5] Claim 11 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

[6] The information disclosure statement filed February 07, 2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

[7] Applicant's arguments filed in Paper No. 16 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[8] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Sequence Compliance

[9] In a transmittal letter filed September 09, 2002, it is noted that applicant states that a computer readable form (CRF) of the amended sequence listing has been submitted. However, the CRF of the sequence listing has not been received and/or entered. Applicants are requested to re-submit a CRF of the sequence listing and include a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

Specification/Informalities

[10] The use of trademarks have been noted in this application (see, e.g., page 10, line 34 and all other instances in the specification). ALL trademarks disclosed in the

specification should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

[11] Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is confusing as the amino acid sequence of SEQ ID NO:8 is only 92 amino acids and it is unclear as to whether applicant intends for the Kunitz-type serine protease inhibitor as recited in claim 1 or 15 to have those additional cysteine residues corresponding to those cysteine residues of SEQ ID NO:52 as recited in claim 18. For example, cysteine at position 152 of SEQ ID NO:52 is not present in SEQ ID NO:8 – does applicant intend for SEQ ID NO:8 to encompass a cysteine at this corresponding residue of a polypeptide comprising SEQ ID NO:8? It is unclear from the claims and the specification as to whether this is a limitation in the recited polypeptide comprising SEQ ID NO:8. It is suggested that applicant clarify the meaning of the claim.

Applicant argues (page 7 of Paper No. 16) the claimed methods recite other Kunitz-type serine protease inhibitors other than SEQ ID NO:8, some of which contain the recited cysteine residues. Applicant argues that the protease inhibitor need only

contain one of the recited disulfide bonds – not all of them. Applicant's argument is not found persuasive.

It is noted that the claims are being examined only to the extent the claims read on the elected subject matter, thus the claims are limited only to a Kunitz-type serine protease inhibitor comprising SEQ ID NO:8. As stated above, the claim is unclear and it is suggested that applicant clarify the meaning of the claim.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[12] Claims 1-10 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 (claims 2-10 dependent therefrom) and 15 (claims 16-18 dependent therefrom) are drawn to a method for accelerating the rate of mucocilliary clearance in a subject by administering to the subject a genus of serine protease inhibitors comprising SEQ ID NO:8 and a physiologically acceptable carrier.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings,

or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of recited serine protease inhibitors comprising SEQ ID NO:8, i.e., SEQ ID NO:1 (and fragments thereof). The specification fails to describe any additional representative species of the recited genus of serine protease inhibitors. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". In the instant case, the recited genus of serine protease inhibitors encompasses that are widely variant in structure, having an infinite number of additional amino acids at the N- or C-terminal ends of SEQ ID NO:8. As such, the species encompassed by the genus encompasses an enormous number of structural variants of SEQ ID NO:8 and the disclosure of the single representative species of serine protease inhibitor is insufficient to be representative of the attributes and features of *all* species encompassed by the

recited genus. Given the lack of description of a representative number of serine protease inhibitors, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

Applicant argues (beginning at page 8 of Paper No. 16) claim 1 has been amended to recite a serine protease inhibitor comprising SEQ ID NO:8 and therefore the issue is whether the recited serine protease inhibitor is adequately described. Applicant argues the specification fully describes the entire genus of recited serine protease inhibitors. Applicant argues the Office was mistaken in its assertion that the specification discloses only a single representative species of the genus of recited serine protease inhibitors, Applicant's argument is not found persuasive.

As stated above, the specification fails to describe the entire genus of serine protease inhibitors comprising SEQ ID NO:8, including *any* additional amino acids at the amino and carboxy termini of SEQ ID NO:8. Contrary to applicant's assertion, the specification discloses only a single representative species of serine protease inhibitors comprising SEQ ID NO:8, i.e., SEQ ID NO:1. The remaining peptides are *fragments* of SEQ ID NO:1 and are thus considered to be encompassed by the disclosure of SEQ ID NO:1.

[13] Claims 1-10 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for accelerating the rate of mucocilliary clearance in a subject by administering to the subject a serine protease

inhibitor of SEQ ID NO:8 and a physiologically acceptable carrier, does not reasonably provide enablement for a method for accelerating the rate of mucocilliary clearance in a subject by administering to the subject *any* serine protease inhibitor comprising SEQ ID NO:8 and a physiologically acceptable carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass a method for accelerating the rate of mucocilliary clearance in a subject by administering to the subject *any* serine protease inhibitor comprising SEQ ID NO:8 and a physiologically acceptable carrier. The broad scope of recited serine protease inhibitors are not commensurate with the enablement provided by the disclosure. The

broad scope of recited serine protease inhibitors encompasses *any* serine protease inhibitor having an infinite number of additional amino acids at the N- or C- termini of SEQ ID NO:8. In this case the disclosure is limited to a method for accelerating the rate of mucocilliary clearance in a subject by administering to the subject a serine protease inhibitor of SEQ ID NO:8 and a physiologically acceptable carrier.

- The lack of guidance and working examples: The specification provides only working examples showing increased mucocilliary clearance using SEQ ID NO:1 or fragments thereof. The specification fails to demonstrate or provide any evidence that all serine protease inhibitors having any number of additional amino acids at the N- or C- termini of SEQ ID NO:8 will successfully increase the rate of mucocilliary clearance. One of skill in the art would expect that additional amino acids at the N- or C-termini of SEQ ID NO:8 will negatively affect interaction of the serine protease inhibitor with its target. However, the specification provides no guidance as to the number of additional amino acids that may be tolerated by SEQ ID NO:8 with an expectation that such additional amino acids will allow for sufficient serine protease inhbition to allow an increase in the rate of mucocilliary clearance.

- The high degree of unpredictability in the art: As the specification fails to provide sufficient guidance regarding the number and/or identity of those amino acids that are tolerated at the N- and C-termini of SEQ ID NO:8, it is highly unpredictable as to the effects of additional amino acids at the N- and C-termini of SEQ ID NO:8. The amino acid sequence of a serine protease inhibitor determines its three-dimensional structure and thus, its ability to interact with its target and, in this case, the ability to increase the

rate of mucocilliary clearance. Predictability of those additional amino acids which can be tolerated and obtain the desired activity requires guidance with regard to the number and identity of those amino acids that may be joined at the N- and C-termini and knowledge of the ways in which those additional amino acids will affect the protein's function. In this case, such guidance has not been provided.

- The amount of experimentation required is undue: While methods of synthetically generating peptides, e.g., peptides having additional amino acids at the N- and C-termini of SEQ ID NO:8 are known in the art, it is not routine in the art to screen for *all* serine protease inhibitors having an infinite number of additional amino acids at the N- and C-termini of SEQ ID NO:8. Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicant argues (beginning at page 10 of Paper No. 16) claim 1 has been amended to recite a serine protease inhibitor comprising SEQ ID NO:8. Applicant argues the specification provides numerous working examples to enable the entire scope of the claimed invention. Applicant's argument is not found persuasive.

While it is acknowledged that working examples of peptides other than SEQ ID NO:8 have been disclosed, e.g., SEQ ID NO:1, it is noted that the claims are not so limited to these working examples, and instead encompass a broad scope of serine protease inhibitors having ANY additional amino acids at the N- or C-termini of SEQ ID NO:8. As discussed above, there is no guidance in the specification as to the number or identity of those additional amino acids that may be fused to SEQ ID NO:8, there is a high degree of unpredictability that additional amino acids will affect the serine protease activity and ability to increase rate of mucocilliary clearance of SEQ ID NO:8, and the amount of experimentation in this regard is far from routine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[14] Claims 1-10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamburini et al. (WO 97/33996) in view of Rasche et al. (*Arzneim*

Forsch 25:110-116) and O'Riordan et al. (*Am J Respir Crit Care Med* 155:1522-1528; cited as reference 17 in the IDS filed February 10, 2000). Claim 1 is drawn to a method for accelerating the rate of mucocilliary clearance in a subject by administering to the subject a serine protease inhibitor comprising SEQ ID NO:8 and a physiologically acceptable carrier. Claims 2-4 limit the method or location of administration of SEQ ID NO:8. Claims 5-9 further limit the aerosol suspension of claim 4. Claim 10 further limits the carrier of claim 1. Claims 15-18 further limit the serine protease inhibitor of claim 1.

Tamburini et al. teach a human placental bikunin, which is a Kunitz-type serine protease (page 2, bottom) having an amino acid sequence (page 3, top) that is 100% identical to SEQ ID NO:1 of the instant application and various fragments thereof (pages 3-7), including SEQ ID NO:8 (page 7), which is 100% identical to SEQ ID NO:8 of the instant application. Tamburini et al. teach human placental bikunin and fragments thereof are contemplated as therapeutics for fibrotic disorders including pulmonary fibrosis (page 22, lines 21-23). Tamburini et al. teach their human placental bikunin and fragments thereof are contemplated for use in the medical/therapeutic applications suggested for native aprotinin (TRYSALOL®) or aprotinin analogues including diseases for which use of the human protein is indicated by virtue of its ability to inhibit human serine proteases such as inhibition of neutrophil elastase for treatment of pulmonary emphysema (page 22, lines 32-34 and page 23, line 13). Tamburini et al. teach various methods of delivery of human placental bikunin for therapeutic use (pages 24-27). Tamburini et al. teach various advantages of using human placental bikunin in place of aprotinin (TRYSALOL ®) such as being of human origin, thus reducing risk of

immunological reaction and being less positively charged than aprotinin thereby reducing the risk of kidney damage (page 24, lines 10-16). Tamburini et al. teach it is highly likely that intra-chain disulfide bond formation occurs and describes those cysteine residues where such disulfide bonds are likely to occur (page 34, bottom, page 35, top). Tamburini et al. do not teach administration of their human placental bikunin and fragments thereof increase the rate of mucociliary clearance in a subject.

Rasche et al. teach a study of inhalation administration of aprotinin (TRYSALOL®) and the effects on patients suffering from chronic obstructive bronchitis including patients suffering from emphasematous pulmonary changes (page 110). Rasche et al. teach two effects of aprotinin (TRYSALOL®) administration were improved expectoration by the patient and a liquification of the sputum (page 116, left column).

O'Riordan et al. generally teach antigen-induced bronchial constriction is associated with mucocilliary clearance and discusses the associated role of neutrophil elastase. Specifically, O'Riordan et al. teach an inhibitor of neutrophil elastase is able to increase mucocilliary clearance as measured by tracheal mucus velocity (TMV) (see, e.g., Figure 2) and suggest that elastase inhibitors may be useful in the treatment of mucociliary disfunction in asthma (page 15427, right column, bottom).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Tamburini et al., Rasche et al., and O'Riordan et al. for a method of accelerating the rate of mucocilliary clearance by administering the human placental bikunin or fragments thereof comprising SEQ ID NO:8 as taught by

Tamburini et al. One would have been motivated for a method of accelerating the rate of mucocilliary clearance by administering the human placental bikunin or fragments thereof comprising SEQ ID NO:8 for therapeutic treatment of pulmonary emphysema, chronic obstructive bronchitis, or asthma as taught or suggested by Tamburini et al., Rasche et al., and O'Riordan et al. One would have a reasonable expectation of success for a method of accelerating the rate of mucocilliary clearance by administering the human placental bikunin or fragments thereof comprising SEQ ID NO:8 because of the results of Tamburini et al. and Rasche et al. or O'Riordan et al. Therefore, claims 1-10 and 15-18, drawn to a method of increasing the rate of mucocilliary clearance as described above would have been obvious to one of ordinary skill in the art.

Double Patenting Rejection(s)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[15] Claims 1-10 and 15-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10

and 15-18 of copending Application 09/218,913 (Application '913). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-10 and 15-18 of the instant application and claims 1-10 and 15-18 of Application '913 are directed to a method for increasing mucocilliary clearance in a subject by administering a composition comprising a Kunitz-type serine protease inhibitor and a physiologically acceptable carrier. Claims 1-10 of the instant application and claims 1-10 of Application '913 differ in that the methods of claims 1-10 of the instant application are limited to a serine protease inhibitor comprising SEQ ID NO:8. Claims 15-18 of the instant application and claims 15-18 of Application '913 differ in that the methods of claims 15-18 of the instant application are limited to a protease inhibitor comprising SEQ ID NO:8, provided that the serine protease inhibitor does not consist of SEQ ID NO:49 or 71, while claim 15 of Application '913 is limited only to SEQ ID NO:8, without the proviso of claim 15 of the instant application. The specification of Application '913 supports an embodiment that would anticipate claims 1-10 and 15-18 herein, i.e., a method for increasing mucocilliary clearance in a subject by administering a composition comprising a Kunitz-type serine protease inhibitor and a physiologically acceptable

carrier, wherein the Kunitz-type serine protease inhibitor comprises SEQ ID NO:8 (see, e.g., page 27, lines 10-15 of Application '913). Claims 1-10 and 15-18 of the instant application cannot be considered to be patentably distinct over claims 1-10 and 15-18 of Application '913 when there are specifically recited embodiments in Application '913 that would anticipate claims 1-10 and 15-18 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

[16] Status of claims:

- Claims 1-11 and 15-18 are pending.
- Claim 11 is withdrawn from consideration as being drawn to a non-elected invention.
- Claims 1-10 and 15-18 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

DAVID STEADMAN
PATENT EXAMINER

10/01/03